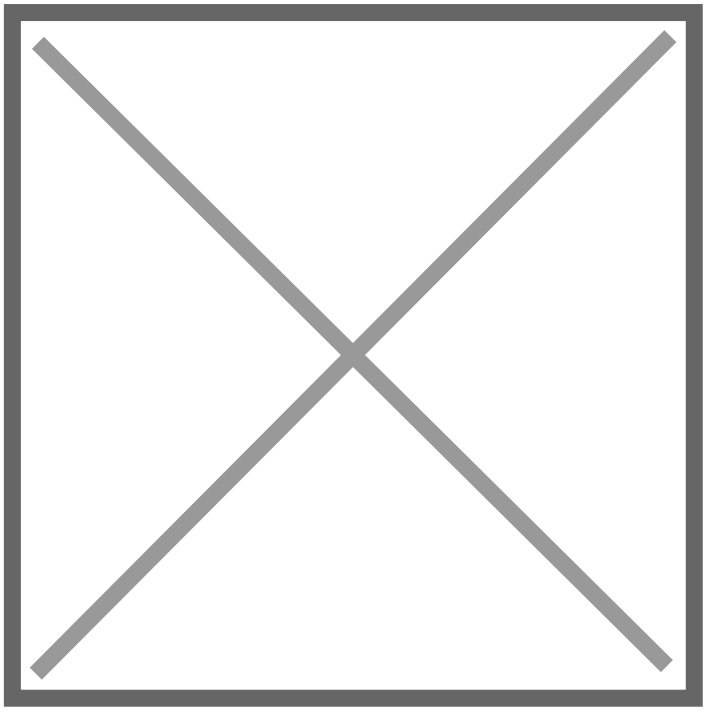


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Flu Vaccine Shortage Hits US

"For years, we made fun of the former Soviet Union for the long queues to pick up perennially short essential items. How is the United States in 2004 any different," wrote an angry American in the New York Times, referring to the night long vigils and mad scramble and rationing for flu vaccines as the nation approached another winter.

What is happening in the US?
Evidently, the flu vaccine is in short supply in October. The government was forced to ration its supply with priority to infants, pregnant women and senior citizens. Flu vaccine supplies disappeared faster than it appeared at health clinics. A biotech major, Chiron Corporation had chartered an aggressive program for meeting the increased American need of influenza vaccines. But its production plans ran into rough weather after British regulators suspended the license for vaccine production due to contamination problems. And the US ran short of the influenza vaccine.

On October 5, 2004, Chiron Corp. notified US government's Center for Disease Control (CDC) that none of its influenza vaccine (Fluvirin) would be available for distribution in the US for the 2004Ã¢â?¬â??05 influenza season. The company indicated that the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom, where Chiron's Fluvirin vaccine is produced, had suspended the company's license to manufacture Fluvirin vaccine in its Liverpool facility for three months, preventing any release of the vaccine for this influenza season.

This action will reduce by approximately one half the expected supply of trivalent inactivated vaccine (flu shot) available in the US for the 2004Ã¢â?¬â??05 season. For sourcing flu shots this year, the US government had heavily relied on Chiron and Aventis, the two major suppliers of the influenza vaccine, but in the present scenario the US officials could widen their options for acquiring flu vaccine from additional suppliers next year or encourage other companies to enter the business, which could cut Chiron's market share in the future.

The question: will Indian companies have an opportunity to tap the demand for flu vaccine? According to some people in the industry, there will be opportunities. But it is not that companies will increase their production. What is more important is that US and other countries may now look at more vendors for sourcing products and not just rely on a few companies.

Chiron had pinned its hopes on its British factory, the erstwhile PowderJect Pharmaceuticals, which it acquired in July 2003 to expand its vaccine business. The company had aimed to double the vaccine production capacity of the plant, located in Liverpool from 26 million vaccine doses in 2002 to 50 million this year. But MHRA's decision has upset the availability of influenza virus vaccine in the US and the revenues of the company. MHRA asserted that Chiron's manufacturing process does not comply with UK Good Manufacturing Practices regulations.

The remaining supply of influenza vaccine expected to be available in the US this season is nearly 58 million doses of Fluzone (inactivated flu shot) manufactured by Aventis Pasteur Inc. Of these doses, approximately 30 million doses have already been distributed by the manufacturer according to CDC. In addition, approximately 3 million doses of live attenuated influenza vaccine (LAIV/FluMist manufactured by MedImmune will be available this season.

The CDC and its Advisory Committee for Immunization Practices (ACIP) is issuing interim recommendations for influenza vaccination during the 2004Ã¢â?¬â??05 season. These interim recommendations were formally recommended by ACIP on October 5, 2004.

There are several stories doing the round. A plausible theory being attributed to this fiasco is pushing the nearly 25-year-old factory beyond its limits. The aging factory was just not able to handle the sudden spurt in its production capacity. But this theory is unfounded, feel the Chiron higher-ups, who claim that about $75 million had been spent to upgrade the factory in the last five years and the company was committed to spend another $100 million to replace a part of the plant. "We take our responsibility to protect human health very seriously," said Howard Pien, president and CEO of Chiron. "Chiron believes in the value of influenza vaccination, and we are committed to taking all necessary actions to ensure an adequate vaccine supply for the 2005-2006 influenza season," he added.

The facility, located in Liverpool, was established in the 1970s and has passed through a series of owners and problems during the last decade. It is reported that Polio vaccines manufactured by Medeva, a previous owner, at the plant were recalled after the British enforcement agencies said they might be contaminated with Bovine Spongiform Encephalitis, or the mad cow disease.

This entire episode could serve as a learning experience for the Indian biomanufacturing industry, which is aiming to be a global biotech-manufacturing hub. Today, India's USP is the speed and cost of R&D. Along with this we should also bear in mind that the quality of the product is equally important. As Kiran Mazumdar-Shaw, chairman and managing director, Biocon said, "Outsourcing is not all about the cost advantage but the quality of deliverables is also important. We should not compete on cost, but on the quality of deliverables".

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